

K963091

## 15 510(k) Summary

This summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

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- 2 Name of Device:  
Trade Name: Vollman Prone Positioner  
Common Name: Patient Positioner  
Classification Name: Manual Patient Rotation Bed
- 3 Predicate Device:  
Stryker Circ-O-lectric Bed Model 460 Preamendment Device  
Stryker Wedge Turning Frame Model 965 Preamendment Device
- 4 Description:  
  
The Vollman Prone Positioner Device is an independent, non-powered, portable accessory to any med-surg or critical care hospital bed with a flat surface that allows an immobile patient with respiratory complications, such as Acute Respiratory Distress Syndrome (ARDS) to be moved from a supine position to a prone position and held there. This position change occurs while the patient remains on either a regulation hospital frame (critical care or med-surg frame) or a therapeutic air support surface. This device allows this position change to be accomplished in most cases with only three caregivers. Currently, the most common method of proning a patient is manually lifting the patient and placing them prone. Other methods of proning a patient are the Stryker Wedge Turning Frame and the Stryker Circ-O-lectric Bed.
- 5 Intended Use:  
  
To assist caregivers in turning patients to or from the supine or prone position. Turning immobile patients can assist in treating pulmonary complications or disorders commonly associated with immobility.
- 6 Technological Characteristics:  
  
All of these devices have metal frames. In each device, the patient is held in place by a manual device such as a strap or padded surface. The Stryker Wedge Turning Frame and the Vollman Prone Positioner are manually-operated devices. The Stryker products have mattresses, where the subject device is an accessory to med-surg and critical care hospital beds with flat mattress surfaces.